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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|-----------------------------|
| 10/016,616 | 10/30/2001 | Mads Gruenberg | 20780 US (C38435/124164) | 6580 |
| 7590 | 09/22/2005 | | | EXAMINER WHALEY, PABLO S |
| Stephen M. Haracz, Esq. BRYAN CAVE LLP 245 Park Avenue New York, NY 10167-0034 | | | ART UNIT 1631 | PAPER NUMBER |

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/016,616 | GRUENBERG ET AL. | |
| | Examiner | Art Unit | |
| | Pablo Whaley | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10/30/2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |



ELECTION/RESTRICTIONS

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I: Claims 1-8 drawn to a method of optimizing a bioprocess involving a complex nutrient mixture, periodically stopping a nutrient supply to decrease microorganism metabolic activity, calculating new feed concentrations, and using an optimization routine to adjust the amount of nutrients supplied to the microorganism, classified in class 700, subclass 028. If this Group is elected, then the below summarized specie election is also required.

Group II: Claim 9 drawn a device for optimized performance of microbiological processes involving complex nutrient mixtures, classified in class 700, subclass 028. If this Group is elected, then the below summarized specie election is also required.

Group III: Claims 10-15 drawn to a method for optimizing production of a fermentation product, classified in class 700, subclass 028. If this Group is elected, then the below summarized specie election is also required.

Group IV: Claim 16 drawn to a fermentation system wherein cultivation of a microorganism is optimized for production of a fermentation product, classified in class 700, subclass 028. If this Group is elected, then the below summarized specie election is also required.

The inventions are distinct and divergent, each from the other because of the following reasons:

The inventions of **Groups I and II** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of **Groups I and II** have different functions. Critical features of Group I that are distinct from Group II include a device that requires sensors and feed controlling elements. Furthermore, Group II does not require periodic and alternating stopping as disclosed in Group I.

The inventions of **Groups I and III** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of **Groups I and III** have different functions. Group I is drawn to a method for optimizing performance of a bioprocess involving a complex nutrient mixtures, and Group II is drawn to a method for optimizing production of a fermentation product. Critical features of Group I that are distinct from Group III include the use of an optimization routine comprising a co-ordination controller and a fuzzy-logic multi-component controller.

The inventions of **Groups II and IV** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of **Groups II and IV** have different effects. Group II is directed to a device for optimized performance of microbial processes involving complex nutrient mixtures. Group IV, on the other hand, is drawn to a fermentation system wherein the cultivation of a microorganism is optimized for production of a fermentation product (i.e. an optimized product). Critical features of Group IV that are distinct from Group II include a means

Art Unit: 1631

for separating nutrients of a complex mixture, means for measuring and controlling pH, pO₂, and temperature, and a device for measuring and controlling the amount of nutrient mixture introduced into the bioreactor.

The inventions of **Groups [I and III]** are independent inventions because they are directed to methods, whereas **Group II** is drawn to a device and **Group IV** is drawn to a fermentation system. Critical features of **Groups [I and III]** that are distinct from Group II and Group IV include the limitations of periodically stopping a supply of each nutrient, and retarding the flow from the first nutrient from the mixture.

Thus, the search for the four groups together would present an undue search burden as they are directed to methods and/or systems that are generally distinct and separate.

MULTIPLE SPECIE ELECTION REQUIREMENT FOR GROUPS I - IV

This application contains claims directed to patentably distinct and divergent species of the claimed inventions. If Group I, II, III, or IV is elected, the applicant is further required to make the following specie elections for purposes of examination. The applicant must elect two of the following species (i.e. elect a single Optimization Routine and single Parameter for determining metabolic activity):

Optimization Routine Election

Specie I-A: Method as set forth in Group I or II, wherein said optimization routine comprises a controller, a multi-component controller, and a means for controlling feed concentration (as disclosed in instant Claim 2).

Specie I-B: Method as set forth in Group I or II, wherein said optimization routine comprises generating a flow chart, generating response times, and using the response times to form the input variable Q_{sens} (as disclosed in instant Claim 4).

Art Unit: 1631

Specie I-C: Method as set forth in Group I or II, wherein said optimization routine is model-based and not disclosed in instant Claim 2 or Claim 4.

Parameter Election

Specie I-D: Method as set forth in Group I or II, wherein the metabolic activity is determined by **one** parameter selected from the following group: oxygen transfer rate, carbon dioxide transfer rate, pH, concentration of dissolved oxygen in the bioreactor, or temperature of the bioreactor.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **Claims 1, 3, and 6-16** are generic to the above species. The species are distinct and divergent because the bodies of literature that describe optimization routines described above are drawn to different functions and thus are not coextensive. Furthermore, the bodies of literature that describe the parameters as stated above for use in determining metabolic activity are not coextensive. Thus, the search for all species together would present an undue search burden as they are directed to separate divergent subject matter.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Art Unit: 1631

Should applicant traverse on the ground that the species are not patentably distinct and divergent, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Because these inventions are distinct and divergent for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the inventions to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am through 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ardin H. Marschel 9/18/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER